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No. 05-273

In the Supreme Court of the United States

FEDERAL TRADE COMMISSION, PETITIONER

v.

SCHERING-PLOUGH CORPORATION, ET AL.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE ELEVENTH CIRCUIT

BRIEF FOR THE UNITED STATES AS AMICUS CURIAE

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QUESTIONS PRESENTED

1. Whether the antitrust laws prohibit a brand name drug patent holder and a prospective generic competitor from settling patent infringement litigation by agreeing that the generic manufacturer will not enter the market before a future date within the term of the patent and that the patent holder will make a substantial payment to the generic manufacturer.

2. Whether the court of appeals erred in concluding that "substantial evidence" did not support the Federal Trade Commission's factual finding that a payment from a patent holder to an allegedly infringing generic manufacturer was consideration for the generic manufacturer's delayed entry into the market rather than a separate royalty for a license concerning a different product.

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This brief is submitted in response to the order of this Court inviting the Solicitor General to express the views of the United States. In the view of the United States, the petition for a writ of certiorari should be denied. The decision below does not conflict with any decisions of this Court or the courts of appeals, and the only important but unsettled issues of federal law that are raised by the petition are not well presented in this case.

STATEMENT

Respondent Schering-Plough Corporation (Schering), a pharmaceutical company, produces and markets a brand-name drug, K-Dur 20, for treating high blood pressure and congestive heart disease. K-Dur 20 contains unpatented potassium chloride encapsulated in an extended release coating that is protected by Schering's United States patent number

4,863,743 (the '743 patent), which expires on September 5, 2006. Pet. App. 2a-3a. Schering sued two of its competitors for proposing to market generic drugs that allegedly would infringe that patent. Thereafter, the parties to those respective suits entered into settlement agreements providing that (1) the defendants would be free to market generic versions of K-Dur 20 as of specified future dates that were earlier than the expiration of the '743 patent, and (2) Schering would make substantial payments to the defendants. The Federal Trade Commission (FTC or Commission) challenged the settlements and held that they violated Section 5 of the Federal Trade Commission Act, 15 U.S.C. 45. The court of appeals vacated the FTC's order. Pet. App. 1a-35a.

1. The two settlements at issue in this case arose in the statutory context created by the Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Act), Pub. L. No. 98-417, 98 Stat. 1585. The Hatch-Waxman Act establishes procedures designed to facilitate the market entry of lower-priced generic drugs while maintaining incentives to invest in new drug development. Under the Act, a company seeking approval from the Food and Drug Administration (FDA) to market a new drug (a "brand name" drug) must file a New Drug Application (NDA) demonstrating the safety and efficacy of its product. 21 U.S.C. 355(b). Once an NDA has been approved, a firm seeking to market a generic version of that drug may file an Abbreviated New Drug Application (ANDA) demonstrating that its product is bioequivalent to the brand-name counterpart. 21 U.S.C. 355(j). The FDA may approve the marketing of a generic drug before the expiration of a patent relating to the brand name drug if the applicant makes a "paragraph IV certification" that the patent in question is invalid or is not infringed by the generic product. 21 U.S.C. 355(j)(2)(A)(vii)(IV). If the patent holder files a patent infringement suit within 45 days after receiving notification

of such a certification, however, the FDA's approval is automatically stayed for 30 months, unless the patent expires or is judicially determined to be invalid or not infringed before that time. 21 U.S.C. 355(j)(5)(B)(iii). The first company to file an ANDA with a paragraph IV certification relating to a particular brand name drug is granted the exclusive right to market a generic version until 180 days after the earlier of two dates: when it begins commercial marketing or when a court holds the patent invalid or not infringed. 21 U.S.C. 355(j)(5)(B)(iv).

2. In 1995, two competitors, Upsher-Smith Laboratories (Upsher) and ESI Lederle, Inc. (ESI), separately filed ANDAs that contained paragraph IV certifications and sought FDA approval to market generic versions of K-Dur-20. Pet. App. 3a-4a & n. 2, 6a n.5. Schering responded by suing each company for patent infringement. In 1997, Schering and Upsher engaged in settlement negotiations, and agreed that Upsher's generic could be marketed on September 1, 2001, five years before expiration of the '743 patent. Upsher, however, "insisted upon its need for cash prior to the agreed entry date," while Schering stated that it "refused to pay Upsher to simply 'stay off the market.'" *Id.* at 4a; see *id.* at 100a, 188a. Ultimately, the parties negotiated, as part of the settlement, an exclusive license under which Schering paid $60 million to Upsher and received the exclusive right to market several Upsher products outside North America, including Upsher's Niacor-SR (Niacor), a cholesterol-reducing drug. *Id.* at 195a-197a.

In the ESI litigation, the court appointed a magistrate judge to supervise mediation. More than a year later, in December 1997, under what the FTC termed "intense, and perhaps unseemly, judicial pressure to settle the patent litigation," Pet. App. 144a, Schering offered to permit ESI to market its generic on January 1, 2004, more than two years before

expiration of the '743 patent. ESI agreed on the date but insisted on a payment. At the magistrate judge's suggestion, Schering then offered $5 million in legal fees. ESI insisted on more, and the magistrate judge and Schering devised a settlement that included an additional payment of $10 million conditioned on ESI's receiving FDA approval for its generic drug by a specified date. *Id.* at 7a.

3. In March 2001, the FTC issued an administrative complaint alleging that the two agreements unreasonably restrained competition in violation of Section 5 of the FTC Act, 15 U.S.C. 45. Pet. App. 48a-49a, 145a; Complaint ¶¶ 68, 69, at 9, *Schering-Plough Corp.*, Docket No. 9297, 2003 WL 22989651 (FTC Dec. 8, 2003). The core allegation was that Schering's cash payments induced Upsher and ESI "to delay launching generic versions of K-Dur 20. Absent those payments, neither Upsher[] nor ESI would have agreed to delay its entry for so long." Complaint ¶ 64, at 8-9.

a. After a two-month administrative trial, the administrative law judge (ALJ) concluded that the challenged agreements "did not unreasonably restrain competition" and dismissed the complaint. Pet. App. 340a. The ALJ found that Complaint Counsel had failed to prove that either payment by Schering was made in exchange for delayed entry. The ALJ determined that the evidence showed that the Upsher licensing agreement was a bona fide agreement and that the $60 million payment from Schering to Upsher represented a fair value for the licenses. *Id.* at 316a-324a. The ALJ also found no "substantial, reliable evidence to conclude that the $15 million was paid [to ESI] only for unlawful delay." *Id.* at 325a.

The ALJ also reasoned that, in order to establish that the settlements had the alleged anticompetitive effect, Complaint Counsel needed to "prove that better settlement agreements or litigation results would have resulted in Upsher[] and ESI

selling their generic equivalents prior to September 1, 2001 and January 1, 2004," *i.e.*, the entry dates agreed upon in the two settlements. Pet. App. 310a. Because Complaint Counsel could not prove that, absent the settlement agreements, either company would have entered the market before the expiration of Schering's patent, *id.* at 310a-312a, 315a, the ALJ concluded that Complaint Counsel had failed to meet its burden of proof, *id.* at 313a-314a.

b. The Commission reversed. Pet. App. 36a-153a. With respect to the Upsher agreement, the FTC found that "there was a direct nexus between Schering's payment and Upsher's agreement to delay its competitive entry and that the magnitude of the payment was not based on Schering's evaluation of the Upsher licenses." *Id.* at 141a. The FTC therefore concluded that "Schering did in fact pay Upsher for delayed entry." *Ibid.* Likewise, because it found no other satisfactory explanation for the $10 million payment from Schering to ESI, the FTC concluded that the ESI payment was in exchange for delayed entry. *Id.* at 144a-145a; see *id.* at 142a n.101.

The FTC explained that the question whether the payments violated the antitrust laws turned on "whether these unconditional payments were likely to have anticompetitive effects because they delayed generic entry beyond the dates that would have been agreed upon in the absence of the payments." Pet. App. 54a. In the Commission's view, that "question can be answered without an inquiry into the merits of the patent litigation." *Ibid.* The FTC reasoned:

> If there has been a payment from the patent holder to the generic challenger, there must have been some offsetting consideration. Absent proof of other offsetting consideration, it is logical to conclude that the quid pro quo for the payment was an agreement by the generic to defer entry

> beyond the date that represents an otherwise reasonable litigation compromise.

Id. at 76a-77a (footnote omitted). Finding no proof of other offsetting consideration for the payments to either Upsher or ESI, the Commission found the agreements illegal. *Id.* at 87a-93a, 141a-145a.

3. The court of appeals set aside the FTC's decision and vacated its remedial order. Pet. App. 1a-35a. In the court's view, it was undisputed that the '743 patent gave Schering "the lawful right to exclude infringing products from the market until September 5, 2006," *i.e.*, the patent's expiration date. *Id.* at 20a. The court found it significant that Complaint Counsel "acknowledged that it could not prove that Upsher and ESI could have entered the market on their own prior to the '743 patent's expiration on September 5, 2006," and that the absence of proof of an alternative entry date "reinforces the validity and strength of the patent." *Ibid.*

The court then turned to the question whether there was "substantial evidence to support the Commission's conclusion that the challenged agreements restricted competition beyond the exclusionary effects of the '743 patent." Pet. App. 20a. With respect to the Upsher agreement, the court noted that the "FTC concede[d] that its position fails if it cannot prove a direct causal link" between the $60 million payment and Upsher's delayed entry into the market. *Id.* at 21a. The court concluded that "the substantial and overwhelming evidence" supported the ALJ's conclusion that the $60 million payment to Upsher represented a bona-fide license payment for Upsher's products. *Id.* at 26a.

With respect to the ESI agreement, the court stated that "there is far less development of the factual record" to support the FTC's conclusion that the ESI settlement was unreasonable. Pet. App. 27a. Moreover, the court observed that the FTC had not rebu''ed the testimony of Schering's experts